

71476 U.S. PTO  
06/17/97

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Lisbeth Illum

Serial No.: Divisional of U.S.S.N. 08/359,937

Express Mail Label No.: EM470185996US

Date of Deposit: June 17, 1997

Filed: December 20, 1994

For: *SMALL PARTICLE COMPOSITIONS FOR  
INTRANASAL DRUG DELIVERY*

Assistant Commissioner for Patents  
Washington, D.C. 20231

REQUEST FOR FILING A DIVISIONAL APPLICATION  
UNDER 37 C.F.R. § 1.60

Sir:

This is a request for filing a Divisional application under 37 C.F.R. § 1.60 of pending prior application Serial No. 08/359,937, filed on December 20, 1994 which is a continuation of Serial No. 08/065,676, filed on May 21, 1993.

I hereby verify that the attached papers are a true copy of what is shown in my records to be the above-identified prior application, including the filed executed declaration, and a copy of the Assignment to Danbiosyst UK Limited. The application includes 1 page of Abstract, 26 pages of Specification, 2 pages of Claims, and 3 sheets of Drawings.

08877273 061797

Enclosed is a Preliminary Amendment. The inventorship for all the claims in this application are the same.

The prior application was assigned of record to Danbiosyst UK Limited, as recorded at reel 6719, frame 0465-0466.

A Power of Attorney by Assignee of Entire Interest and Revocation of Prior Powers as filed in the prior application is enclosed.

A check in the amount of \$385.00 is enclosed to cover the filing fee. The filing fee has been calculated on the basis of the claims remaining after entry of the attached Preliminary Amendment. It is believed that this is the proper filing fee since the application will include 1 independent claim and a total of 14 claims after entry of the Preliminary Amendment.

A Verified Statement Claiming Small Entity Status for Danbiosyst UK Limited was filed in the parent application and such status is still proper.

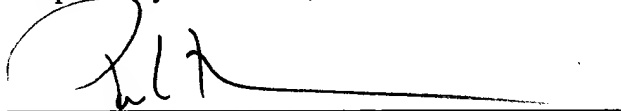
The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 01-2507. A duplicate copy of this request is enclosed.

This application is being filed on June 17, 1997, by mailing the application to Commissioner of Patents and Trademarks, Washington, DC 20231 via the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 C.F.R. § 1.10.

The Express Mail Label No. appears in the heading of this paper which is attached to the application papers pursuant to 37 C.F.R. §1.10(b).

I hereby declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,



Patrea L. Pabst  
Reg. No. 31,284

Date: June 17, 1997

ARNALL GOLDEN & GREGORY LLP  
2800 One Atlantic Center  
1201 West Peachtree Street  
Atlanta, Georgia 30309-3450  
(404) 873-8794

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that this REQUEST FOR FILING A DIVISIONAL APPLICATION and any documents referred to as attached therein are being deposited with the United States Postal Service on this date, June 17, 1997, in an envelope as "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10, Mailing Label Number EM470185996US, addressed to Assistant Commissioner for Patents, Washington, D.C. 20231.



Eva Mukasa

Date: June 17, 1997

CERTIFICATE UNDER 37 C.F.R. § 3.73(b)

Patentees: Lisbeth Illum

U.S. Patent Application No.: Divisional of 08/359,937 Issued: To be Assigned

For: SMALL PARTICLE COMPOSITIONS FOR INTRANASAL DRUG DELIVERY

Danbiosyst U.K. Limited, a Corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of:

An assignment of the patent application identified above from Lisbeth Illum to Danbiosyst U.K. Limited, was recorded in the Patent and Trademark Office at Reel 6719, Frame 0465-0466.

OR

A chain of title from the inventor(s), of the patent application identified above, to the current assignee as shown below:

1. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.
2. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

[ ] Additional documents in the chain of title are listed on a supplement sheet.

[ ] Copies of assignments or other documents in the chain of title are attached.

The undersigned has reviewed all the documents in the chain of title of the patent application identified above and, to the best of undersigned's knowledge and belief, title is in the assignee identified above.

The undersigned (whose title is supplied below) is empowered to act on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date : June 17, 1997  
Name : Patricia L. Fabsi  
Title : Att. of Record Rep. No. 31,284  
Signature : [Signature]

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Serial No.: 08 / 065,676

Group No.:

Filed: May 21, 1993

Examiner:

For: Lisbeth Illum "Small Particle Compositions For Intranasal Drug Delivery"

Commissioner of Patents and Trademarks

Washington, D.C. 20231

ATTENTION: Application Division

COMPLETION OF FILING REQUIREMENTS

(check and complete this item, if applicable)

- I. ☒ This replies to the Notice to File Missing Parts of Application (PTO-1533) mailed June 22, 1993

NOTE: If these papers are filed before the office letter issues adequate identification of the original papers should be made, e.g., in addition to the name of the inventor and title of invention, the filing date based on the "Express Mail" procedure, the serial number from the return post card or the attorney's docket number added.

- ☒ A copy of the Notice to File Missing Parts of Application—Filing Date Granted (Form PTO-1533) is enclosed.

NOTE: The PTO requires that a copy of Form PTO-1533 be returned with the response to the notice to file missing parts to the application.

DECLARATION OR OATH

- II. ☒ No original declaration or oath was filed and enclosed is the original declaration or oath for this application.

CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any paper referred to as being transmitted therewith) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Anna-louise Owens

(Type or print name of person mailing paper)

Date: July 9, 1993

*Anna Louise Owens*

(Signature of person mailing paper)

0887273-061793

OR

- ☐ The original declaration or oath which was filed was determined to be defective. A new original oath or declaration is attached.

NOTE: 37 CFR 1.41(a) points out that "Full names must be stated, including the family name and at least one given name without abbreviation together with any other given name or initial."

NOTE: For surcharge fee for filing declaration after filing date complete item VI(3) below.

NOTE: Acceptable minimums in the declaration for identification of the specification to which it applies are the name of the inventor and (1) serial number (2) attorney docket number which was on the application as filed and the filing date (3) title of the invention and filing date (4) title of invention and reference to a specification which is attached to the declaration at the time of execution and filed with the declaration or (5) title of invention and a statement by a registered attorney that the application filed in the PTO is the application which the inventor executed by signing the declaration. If identification (4) is used it must be accompanied by a statement that the "attached" specification is a copy of the specification and any amendments thereto which were filed in the PTO to obtain the filing date; such a statement must be a verified statement if made by a person not registered to practice before the PTO. Notice of September 12, 1983 (1035 O.G. 3).

NOTE: Another minimum found acceptable in the declaration is the filing date (i.e., date of express mail) and the express mail number, useful where the serial number is not yet known. But note the practice where the express mail deposit is a Saturday, Sunday or holiday within the District of Columbia. 37 CFR 1.10(c).

(complete (c) or (d), if applicable)

Attached is a

- (c) ☐ Statement by a registered attorney that the application filed in the PTO is the application which the inventor executed by signing the declaration.
- (d) ☐ Statement that the "attached" specification is a copy of the specification and any amendments thereto which were filed in the PTO to obtain the filing date.

#### AMENDMENT CANCELLING CLAIMS

- III. ☐ Cancel claims \_\_\_\_\_ inclusive.

#### TRANSMITTAL OF ENGLISH TRANSLATION OF NON-ENGLISH LANGUAGE PAPERS

IV.

- ☐ Submitted herewith is a verified English translation of the non-English language application papers as originally filed. It is requested that this translation be used as the copy for examination purposes in the PTO.

NOTE: For fee processing a non-English application complete item VI(5) below.

NOTE: A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 CFR 1.69(b).

NOTE: The translation for a regular application filed in a foreign language must be verified. 37 CFR 1.52(d).

#### SMALL ENTITY STATUS

V.

- ☒ A verified statement that this filing is by a small entity

NOTE: If an original verified statement and a refund request is filed within two months of the date of payment of a fee then the excess fee paid will be refunded on request. 37 CFR 1.28(a).

(Completion of Filing Requirements [5-1]—page 2 of 5)

0887273 061797  
264790 672680

(check and complete applicable items)

☒ is attached

☒ a separate refund request accompanies this paper

☐ was filed on \_\_\_\_\_ (original)

### COMPLETION FEES

#### VI.

**WARNING:** Failure to submit the surcharge fees where required will cause the application to become abandoned. 37 CFR 1.53(d).

**NOTE:** The filing fees, fees for claims and surcharge fees listed below in items 1, 2 and 3 are reduced by 50% where proof of a small entity status is established on or before the date the fee is paid. If the full fee was paid but a verified statement is filed within 2 months of the date of timely payment of a fee then the excess fee paid will be refunded on request. 37 CFR 1.28(a).

##### 1. Filing fee

☐ original patent application (37 CFR 1.16(a))—\$690.00; Small entity—\$345.00

\$ \_\_\_\_\_

☐ design application (37 CFR 1.16(f))—\$280.00; small entity—\$140.00

\$ \_\_\_\_\_

\$ \_\_\_\_\_

##### 2. fees for claims

☐ each independent claim in excess of 3 (37 CFR 1.16(b))—\$72.00; small entity—\$36.00

\$ \_\_\_\_\_

☐ each claim in excess of 10 (37 CFR 1.16(c))—\$20.00; small entity—\$10.00

\$ \_\_\_\_\_

☐ multiple dependent claim(s) (37 CFR 1.16(d))—\$220.00; small entity—\$110.00

\$ \_\_\_\_\_

##### 3. surcharge fees

☐ late payment of filing fee

and/or

☒ late filing of original declaration or oath (37 CFR 1.16(e))—\$130.00; small entity—\$65.00;

\$ 65 \_\_\_\_\_

**NOTE:** Even where a facsimile declaration or oath signed by the inventor(s) was part of the originally filed papers the surcharge fee is required.

**NOTE:** If both the filing fee and declaration or oath were missing from the original papers only one surcharge fee for both need be paid. 37 CFR 1.16(e).

4. ☐ petition and fee for filing by other than all the inventors or a person not the inventor (1.47—\$130.00)

\$ \_\_\_\_\_

5. ☐ fee for processing an application filed with a specification in a non-English language (37 CFR 1.17(k) and 1.52(d))—\$130.00

\$ \_\_\_\_\_

6. ☐ fee for processing and retention of application  
(37 CFR 1.21(l) and 1.53(d))—\$300.00

\$ \_\_\_\_\_

NOTE: 37 CFR 1.21(l) establishes a fee for processing and retaining any application which is abandoned for failing to complete the application pursuant to 37 CFR 1.53(d) and this, as well as, the changes to 37 CFR 1.53 and 1.78 indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee or the processing and retention fee of § 1.21(1) within 1 year of notification under §1.53(d) must be paid.

Total completion fees

\$ 65

#### EXTENSION OF TIME

#### VII.

(complete (a) or (b) as applicable)

The proceedings herein are for a patent application and the provisions of 37 CFR 1.136(a) apply.

- (a) ☐ Applicant petitions for an extension of time, the fees for which are set out in 37 CFR 1.17(a)-(d), for the total number of months checked below:

Extension (months)	Fee for other than small entity	Fee for small entity
<input type="checkbox"/> one month	\$ 110.00	\$ 55.00
<input type="checkbox"/> two months	\$ 350.00	\$175.00
<input type="checkbox"/> three months	\$ 810.00	\$405.00
<input type="checkbox"/> four months	\$1,280.00	\$640.00

Fee \$ \_\_\_\_\_

If an additional extension of time is required please consider this a petition therefor.

(check and complete the next item, if applicable)

- ☐ An extension for \_\_\_\_\_ months has already been secured and the fee paid therefor of \$ \_\_\_\_\_ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ \_\_\_\_\_

or

- (b) ☐ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

#### TOTAL FEE DUE

#### VIII.

The total fee due is

Completion fee(s) \$ 65

Extension fee (if any) \$ \_\_\_\_\_

TOTAL FEE DUE \$ 65



PAYMENT OF FEES

IX.

- ☒ enclosed is a check in the amount of \$ 65
- ☐ charge Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_
- A duplicate of this request is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 CFR 1.22(b).

AUTHORIZATION TO CHARGE ADDITIONAL FEES

X.

WARNING: Accurately count claims, especially multiple dependant claims, to avoid unexpected high charges if extra claims are authorized.

- ☒ The Commissioner is hereby authorized to charge the following additional fees which may be required by this paper and during the pendency of this application to Account No. 12-2147

☐ 37 CFR 1.16 (a), (f) or (g) (filing fees)

☒ 37 CFR 1.16 (b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

- ☒ 37 CFR 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)

- ☒ 37 CFR 1.17 (application processing fees)

WARNING: While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a) this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 CFR 1.136(a) is to no avail unless a request or petition for extension is filed." (Emphasis added). Notice of November 5, 1985 (1060 O.G. 27).

- ☐ 37 CFR 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 CFR 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.311(b).

NOTE: 37 CFR 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee". From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

Reg. No. 20,570

Tel. No.: (617) 227-0700

SIGNATURE OF ATTORNEY

Scott R. Foster

Type or print name of attorney

Lorusso & Loud

P.O. Address

440 Commercial St. Boston, MA 02109

71406 U.S. PAT. & TM. OFF. 09/17/99

1082

Date: 17, 1997

Case Docket No. WC103DIV 20260/10

ASSISTANT COMMISSIONER FOR PATENTS  
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is the patent application of  
Inventors: Lisbeth Illum  
For: SMALL PARTICLE COMPOSITIONS FOR INTRANASAL DRUG DELIVERY

Enclosed are:

- ☒ 1 page Abstract, 26 pages of Specification, 2 pages of Claims and 3 sheets of Drawings (informal).
- ☒ A copy of an assignment of the invention to Danbiosyst
- ☐ A certified copy of a \_\_\_\_\_ application.
- ☐ An associate power of attorney.
- ☒ A verified copy statement to establish small entity status under 37 CFR 1.9 and 37 CFR 1.27.

The filing fee has been calculated as shown below:

	(Col. 1)	(Col. 2)
FOR:	NO. FILED	NO. EXTRA
BASIC FEE		
TOTAL CLAIMS	14-20 =	*0
INDEP CLAIMS	1-3 =	*0
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENTED		

\* If the difference in Col. 1 is less than zero, enter "0" in Col. 2.

SMALL ENTITY		OR	OTHER THAN A SMALL ENTITY	
RATE	FEE		RATE	FEE
	\$385	OR		\$770
x 11 =	\$0	OR	x 22 =	\$0
x 40 =	\$0	OR	x 80 =	\$0
x130 =	\$0	OR	x260 =	\$0
TOTAL	\$385	OR	TOTAL	\$

- ☒ Please charge my Deposit Account No. 01-2507 in the amount of \$385.00. A duplicate copy of this sheet is enclosed.
- ☒ Checks in the amount of \$385.00 and \$55.00 are enclosed.
- ☒ The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 01-2507. A duplicate copy of this sheet is enclosed.
  - ☒ Any additional filing fees required under 37 CFR 1.16.
  - ☒ Any patent application processing fees under 37 CFR 1.17.
- ☒ The Commissioner is hereby authorized to charge payment of the following fees during the pendency of this application or credit any overpayment to Deposit Account No. 01-2507. A duplicate copy of this sheet is enclosed.
  - ☒ Any patent application processing fees under 37 CFR 1.17.
  - ☐ The issue fee set in 37 CFR 1.18 at or before mailing of the Notice of Allowance, pursuant to 37 CFR 1.311(b).
  - ☒ Any filing fees under 37 CFR 1.16 for the presentation of extra claims.

Respectfully submitted,

Patrea L. Babst, Reg. No. 31,284